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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,573	04/06/1999	DAVID R. WALT	A-67207-2/DJB/RMS/DCF	6459

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/287,573	WALT ET AL.
	Examiner	Art Unit
	Gailene R. Gabel	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001 and 26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-48* is/are pending in the application.

4a) Of the above claim(s) *16-19,23-26,40-45 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22,27-39,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III, claims 20-22, 27-39, 46, and 47, with traverse, filed 1/26/04, is acknowledged and has been entered. Applicant arguments filed 5/21/01 are also acknowledged. Claims 16-19, 23-26, 40-45, and 48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 16-48 are pending. Claims 20-22, 27-39, 46, and 47 are under examination.

2. Applicant argues that Group III is generic and Group I and IV are proper species of the Group III genus. According to Applicant, all the elements recited in Group III are found in Groups I and IV; thus, Group III satisfies the requirements for a genus claim. Applicant contends that the commonality between Groups I, III, and IV should prevent restriction between the inventive groups. Additionally, Applicant argues that search and examination of all three groups does not pose serious burden to Examiner due to the commonality in all three groups.

Applicant's argument is not found persuasive because restriction requirements are set forth for reasons of patentable distinction, despite some apparent commonalities, between each independent invention; thus, warranting separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from

the other or independent from the other. Additionally, Examiner has met her burden of demonstrating that each of the Groups is patentably distinct from the others by showing that each group has separate structural and functional requirements and as such, has a separate status in the art as shown by their different classifications. Therefore, literature search for each method is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL for reasons of record.

Rejections Withdrawn

Claim Rejections - 35 USC § 103

3. In light of Applicant's amendment and argument, the rejection of claims 20-22 and 27-39 under 35 USC § 103(a) as being unpatentable over Walt et al. (US 6,023,540), is hereby, withdrawn.

4. In light of Applicant's amendment and argument, the rejection of claims 27 and 32-39 under 35 U.S.C. 103(a) as being unpatentable over Rushbrook et al. (GB 2294319A), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-22, 27-39, 46, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite in depending from a non-elected claim.

Claim 27, step c) is indefinite in lacking clear antecedent support in reciting, "from at least first and second sensor elements" since step a) recites "subpopulations of sensor elements". Does Applicant intend, "of at least a first and a second sensor element". Please clarify.

Claim 27, step c) is ambiguous in reciting, "from at least a first subpopulation" without a recitation of "a second population" in the given set of claims.

Claim 28 is indefinite in depending from a non-elected claim.

Claim 32 is indefinite in depending from non-elected claims.

Claim 33 is indefinite in depending from non-elected claims.

Claim 34 is indefinite in depending from non-elected claims.

Claim 35 is indefinite in depending from non-elected claims.

Claim 39 lacks clear antecedent support in reciting, "said population" in relation to claim 38 from which it depends, because claim 38 recites "at least two populations".

Claim 46 is indefinite in depending from non-elected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 27-39, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196).

Pinkel et al. disclose a method of simultaneous measurement of target analytes wherein an optical fiber array having a plurality of subpopulations of sensor elements (optical fibers bundled together) is provided and contacted with a sample comprising target analytes. Each sensor element is uniquely addressed and bears distinct bioactive agents (biological binding partner) present in the optical fiber array bearing multiple species (see column 3, line 39 to column 4, line 26). The bioactive agents which are uniquely addressed include oligonucleotides, nucleic acids, and proteins (see column 3, lines 8-22, column 4, lines 27-34 and 55-67 and column 6, lines 30-39). Pinkel et al. teach that use of concave or convex sensor ends provides a greater surface area upon which to immobilize the bioactive agents to thus, increase the signal to noise ratio per optical fiber of the biosensor (see column 8, lines 22-25). The substrate used includes glass or plastic (see column 11, lines 50-55). A detector can be arranged to read signals and obtain simultaneous measurements, i.e. first and second measurements, from a single sensor element of the optical fiber or from a group of sensor elements from a population or bundle of optical fibers (see column 9, lines 23-57). By examining the uniquely addressed transmission ends of fibers or groups of fibers, the addressed transmission ends can transmit unique patterns for rapid identification and measurement of analytes by the sensor (see column 4, lines 21-25).

The detector system may also be equipped with a computerized data acquisition system and analytical program to perform automated statistical analysis and validity of all measurements obtained from the sensor elements so that diverse parameters, i.e. mean, standard deviation, outliers, are statistically and concurrently analyzed and correlated (see column 13, lines 33-56).

Pinkel et al. is silent in specifically teaching that the parameters analyzed from the results include mean, standard deviation, outliers (outside standard deviation), confidence intervals, hypothetical testing, cluster analysis, as recited in claims 31, 32, 33, 34, 36, 37, and 39. However, statistical analysis strategies, i.e. calculating mean/average, standard deviation, precision/ repeatability of a method as reflected in a second analysis, confidence intervals, correlation studies, and distribution/cluster analysis and evaluation are standard laboratory practice and a required optimization procedure in immunological assays and methods. Since Applicant has not disclosed that the specific limitations recited in instant claims 31, 32, 33, 34, 36, 37, and 39 are for any particular purpose or solve any stated problem, absent unexpected results, it would have been obvious for one of ordinary skill to use statistical analysis strategies known and conventionally used in chemical and immunological art.

7. Claims 20, 22, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196) in view of Stimpson et al. (US Patent 5,559,668).

Pinkel et al. has been discussed supra. Pinkel et al. differ from the instant invention in failing to teach that the sensor elements are beads in an array dispersed on a substrate selected from glass or plastic.

Stimpson et al. disclose a waveguide binding assay method wherein an array comprising a plurality of subpopulations of light scattering beads (particles) are sensor elements for binding with target analytes (see Abstract and column 16, lines 27-64). The beads are colloidal metals such as gold and are dispersed on a substrate (waveguide or element) composed of either plastic or glass (see column 10, lines 33-59). Stimpson et al. also disclose that location of each of sensor element within the arrays can be configured, located, and identified (see columns 11 and 12).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the light scattering beads for use as sensor elements as taught by Stimpson into the optical fiber array used in the method of Pinkel because Stimpson specifically taught that light scattering beads, used as sensor elements, can increase acquisition of data or results by two orders of magnitudes by simultaneous interrogation; thus, allowing simultaneous measurements of the beads at multiple sites of an array and permitting extremely rapid acquisition of data.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent 5,837,196) in view of Stimpson et al. (US Patent 5,559,668) as applied to claims 20, 22, and 47 above, and in further view of Sadana et al. (Sensors and Actuators B-Chemical, 32 (3): 195-201).

Pinkel et al. and Stimpson et al. have been discussed supra. Pinkel et al. and Stimpson et al. differ from the instant invention in failing to teach that the substrate upon which the beads are dispersed is a fiber optic bundle. (See Abstract).

Sadana et al. teach beads dispersed on a fiber-optic bundle, which is an antibody-based biosensor for use in fractal analysis method.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Sadana in dispersing beads on a fiber-optic bundle into the method of Pinkel as modified by Stimpson because Stimpson specifically taught that light scattering beads, used as sensor elements in the method of Pinkel, can increase acquisition of data or results by simultaneous interrogation; thus, allowing simultaneous measurements of the beads at multiple sites of an array and permitting extremely rapid acquisition of data and Sadana specifically taught application of such beads on a fiber optic bundle in an antibody-based biosensor.

Response to Arguments

9. Applicant's arguments filed 5/21/01 have been fully considered but they are not persuasive.

A) Applicant argues that Pinkel fails to teach or suggest a method for increasing the signal-to-noise ratio of a sensor array.

In response, the feature upon which applicant relies (i.e., a method for increasing the signal-to-noise ratio) is not recited in the rejected claims. Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B) Applicant argues that Pinkel fails to teach a method of amplifying the optical response of a sensor array.

In response, the feature upon which applicant relies (i.e., a method of amplifying the optical response of a sensor array) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

C) Applicant argues that Pinkel fails to teach summing the optical responses of a sensor array.

In response, the feature upon which applicant relies (i.e., summing the optical responses of a sensor array) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D) Applicant argues that Pinkel fails to teach summing the optical responses in order to increase signal-to-noise ratio and amplify the signal.

In response, the feature upon which applicant relies (i.e., summing the optical responses in order to increase signal-to-noise ratio and amplify the signal) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

E) Applicant argues that Pinkel does not teach performing statistical analysis on the measurements obtained from the responses of the sensor elements.

Contrary to Applicant's argument, Pinkel indeed teach performing statistical analysis of results in column 13, lines 33-56 wherein the detector system is equipped with a computerized data acquisition system and analytical program to perform automated statistical analysis and validity of all measurements obtained from the sensor elements so that diverse parameters, i.e. mean, standard deviation, outliers, are statistically and concurrently analyzed and correlated.

10. For reasons aforementioned, no claims are allowed.

11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1641
April 15, 2004

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04/19/04